2018 Current Fiscal Year Report: Patient Engagement Advisory Committee

Report Run Date: 06/05/2019 12:25:12 PM

1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018
3. Committee or Subcommittee	**3b. GSA Committee No.**
Patient Engagement Advisory Committee	2532

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	10/06/2017	10/06/2019	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 394	10/06/2015	Continuing	No

15. Description of Committee Non Scientific Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 1 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 1

Meetings and Dates

Purpose	Start	End

On October 11-12, 2017, the Patient Engagement Advisory Committee met to discuss and make recommendations on the topic of patient input into medical device clinical trials, specifically, patient involvement in the design of clinical trials; patient recruitment, enrollment and retention; and communication of study results to trial participants. During the meeting, open public hearing speakers included patients, research organizations, industry, patient advocacy groups, and other members of the public. Design of clinical trials: The Committee discussed opportunities and barriers patients experience when attempting to collaborate with industry on the design of clinical trials. The Committee agreed that FDA and Industry must develop a framework to de-mystify the clinical trial process by directing patients to clinical trial information and by addressing the barriers patients face. Enrollment and Retention: The Committee discussed challenges of trial design that contribute to retention issues for patient enrollment. It endorsed taking time to educate patients prior to, during, and after the trial; using simpler language in patient education materials; increasing the diversity of trial participants by involving underrepresented investigators; and ensuring meaningful outcomes for patients when designing clinical trials. It also recommended aggressive outreach, clearly delineating what is expected of participants throughout the trial, and clearly distinguishing the length of time the patient will be required participate. The Committee discussed the most effective means of recruiting patients, recommending strengthening strategic partnerships with other patient groups, physicians and organizations; obtaining patient feedback and recommendations to utilize as the best practice to design clinical studies that support retention; and utilizing more flexible inclusion/exclusion criteria to help obtain more patients in the rare disease arena. To retain trial participants, it recommended obtaining feedback from family as well as patients; setting expectations; extending common courtesies; and valuing the patient as a person. The Committee discussed factors to be considered when communicating clinical trial results to the trial participants and to the public, emphasizing the importance of detailing the communication plan as part of the protocol development process; using accessible and easy to read communication; and sharing results to keep the patients engaged with clinical research.	10/11/2017 - 10/12/2017

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$13,958.00	$19,140.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$156,322.00	$214,460.00
18a(4). Personnel Pmts to Non-Member Consultants	$557.00	$1,641.00
18b(1). Travel and Per Diem to Non-Federal Members	$7,596.00	$11,472.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$1,796.00	$1,807.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$73,045.00	$105,082.00
18d. Total	$253,274.00	$353,602.00
19. Federal Staff Support Years (FTE)	1.00	1.25

20a. How does the Committee accomplish its purpose?

The Committee provides advice to the Commissioner of Food and Drugs on complex issues relating to medical devices, the regulation of devices, and their use by patients. Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes and device-related quality of life or health status issues are among the topics that may be considered by the Committee. The Committee provides relevant skills and perspectives in order to improve communication of benefits,

risks and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

20b. How does the Committee balance its membership?

The Patient Engagement Advisory Committee charter specifies that the Committee shall consist of a core of 9 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities who are knowledgeable in areas such as clinical research, primary care patient experience, healthcare needs of patient groups in the United States, or are experienced in the work of patient and health professional organizations, methodologies for eliciting patient preferences, and strategies for communicating benefits, risks and clinical outcomes to patients and research subjects. The core of voting members may include 1 technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and are recommended by either a consortium of consumer-oriented organizations or other interested persons.

20c. How frequent and relevant are the Committee Meetings?

The Patient Engagement Advisory Committee charter specifies that meetings shall be held approximately twice annually. During the meetings the Committee will provide advice to the Commissioner of Food and Drugs on complex issues relating to medical devices, the regulation of devices, and their use by patients. One meeting was held in FY 2018 to discuss clinical trial issues and two meetings are planned for FY 2019.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

The Committee provides relevant skills and perspectives in order to improve communication of benefits, risks and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. The alternate means of accessing this advice would involve the recruitment of large numbers of specialists on a full-time basis at maximum rates of compensation.

20e. Why is it necessary to close and/or partially closed committee meetings?

Not Applicable

21. Remarks

The committee met once in FY 2018. In addition, considerable time was devoted to maintaining associated records, and streamlining paper processes within FDA. In

addition, time was spent in the routine care and maintenance of the committee: the development of a financial report for this website; updating the roster on our website; completing the annual ethics report; reviewing financial disclosures of current members and providing ethics training.

Designated Federal Officer

Letise Williams Program Analyst, Center for Devices and Radiological Health, FDA

Committee Members	Start	End	Occupation	Member Designation
Chauhan, Cynthia	05/22/2017	04/30/2020	Patient Advocate, Mayo Clinic Breast Ctr, Mayo Clinic, Rochester, MN	Special Government Employee (SGE) Member
Conway, Paul	05/22/2017	04/30/2021	President, Amer. Assoc. of Kidney Patients, Tampa, FL	Special Government Employee (SGE) Member
Cornwall, Deborah	05/22/2017	04/30/2019	Managing Director, The Corlund Grp., Marshfields Hills, MA	Special Government Employee (SGE) Member
Downs, Jr., Frederick	05/22/2017	04/30/2019	Prosthetics, Rehabilitation, Orthotics; Fort Washington, MD	Special Government Employee (SGE) Member
Dunlap, Bennet	05/22/2017	04/30/2020	Diabetes patient Advocacy, Health Communication Consultant, Bryn Athyn, PA	Special Government Employee (SGE) Member
Leong, Amye	05/22/2017	04/30/2021	Pres. & CEO, Healthy Motivaton, Santa Barbara, CA	Special Government Employee (SGE) Member
Schrandt, Mary	05/22/2017	04/30/2019	Dir. Patient Engagement, Arthritis Foundation, Atlanta, GA	Special Government Employee (SGE) Member
Seelman, Katherine	05/22/2017	04/30/2021	Consumer Representative, Prof. Emerita, Schl. of Health & Rehab, Pittsburgh, PA	Special Government Employee (SGE) Member
Willis-Parker, Monica	05/22/2017	04/30/2020	Dir. Minority Engagement Core, Emory Alzheimer's Disease Res. Ctr., Atlanta, GA	Special Government Employee (SGE) Member

Number of Committee Members Listed: 9

Narrative Description

FDA’s strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Patient Engagement Committee supports FDA's strategic priorities by providing advice to the Commissioner of Food and Drugs on complex issues relating to medical devices, the regulation of devices, and their use by patients. Topics to be considered by the Committee include Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes and device-related quality of life or health status issues. The Committee performs its duties by identifying new approaches, promoting innovation,

recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy. This supports the development of safe and effective new medical technologies, and advances the status of the Agency as a science-based and science-led regulatory agency, providing global leadership in the protection of public health.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓
Under $100,000	
$100,000 - $500,000	
$500,001 - $1,000,000	
$1,000,001 - $5,000,000	
$5,000,001 - $10,000,000	
Over $10,000,000	
Cost Savings Other	

Cost Savings Comments

The utilization of the Patient Engagement Advisory Committee enables the Agency to obtain required services from experts who are knowledgeable in areas such as clinical research, primary care patient experience, and health care needs of patient groups in the United States not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the

committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?
1

Number of Recommendations Comments
The committee made 1 recommendation since its establishment in FY 2016 through FY 18 - See Meeting Purposes and Dates and question 20a of the annual report or specific accomplishments.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
0%

% of Recommendations Fully Implemented Comments
The function of the committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
100%

% of Recommendations Partially Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?
Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments
The Agency is developing a guidance document to address the committee's recommendation. The guidance document and other general matters issues will be available publically when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	✓
Reallocated resources	
Issued new regulation	
Proposed legislation	
Approved grants or other payments	
Other	✓

Action Comments

The committee will address patient related issues and take appropriate programmatic steps.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

Not Applicable

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	✓
Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	✓
Other	

Access Comments

Not Applicable